



## ENZYMATIC THERAPY

INCORPORATED

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December 22, 2005

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Tyler Encapsulations < Vitamine Formulas

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Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467 6

### ENZYMATIC THERAPY™

&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

DEC 23 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Omega Sustain™	Improve your mood*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Michael P. Devereux  
Chief Operations Officer

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## ENZYMATIC THERAPY INCORPORATED

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December 21, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Omega Sustain™	Increase your energy*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation for the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Omega Sustain™	Reduce your stress*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

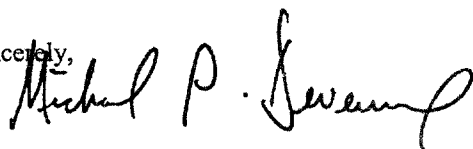
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

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Michael P. Devereux  
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Omega Sustain™	Supports serotonin levels to resist the effects of stress*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12/21/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Omega Sustain™	Omega Sustain with Omega-3 Fatty Acids supports serotonin levels to resist the effects of stress.*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

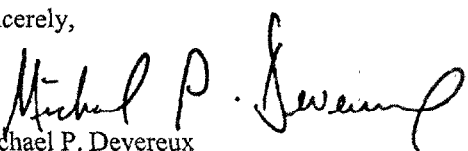
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

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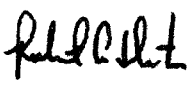
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Omega Sustain™	EPA is a precursor for the formation of prostaglandins, compounds that play a role in hormone regulation.*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

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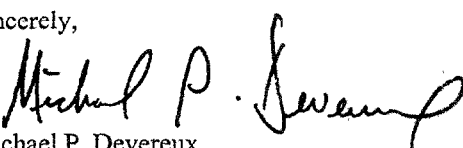
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Omega Sustain™	Supplementation supports healthy mental function and promotes a positive outlook.*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

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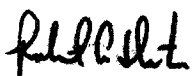
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Omega Sustain™	Research has shown that DHA supplementation can enhance learning ability and promote a positive outlook.*	Fish Oil Concentrate providing 600 mg Omega-3 Fatty Acids as: EPA (Eicosapentaenoic Acid), DHA (Docosahexaenoic Acid)

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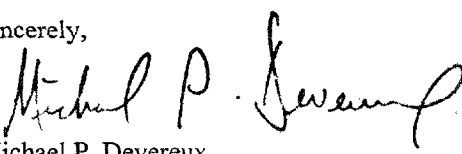
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